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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,763	11/18/2005	Francine Gervais	50291/014002	9212
21559	7590	03/28/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EMCH, GREGORY S	
			ART UNIT	PAPER NUMBER
			1649	
			NOTIFICATION DATE	DELIVERY MODE
			03/28/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,763	<b>Applicant(s)</b> GERVAIS ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-40, drawn to a method of preventing or treating an amyloid- $\beta$  related disease in a subject, said method comprising administering to a subject in need thereof an effective amount of a first agent that prevents or treats amyloid- $\beta$  related disease, and a second agent that is (i) a peptide or peptidomimetic that modulates amyloid- $\beta$  fibril formation or induces a prophylactic or therapeutic immune response against amyloid- $\beta$  fibril formation, or (ii) an immune system modulator that prevents or inhibits amyloid- $\beta$  fibril formation.

Group II, claim(s) 41-78, drawn to a pharmaceutical composition for treating a subject comprising a first agent that prevents or treats amyloid- $\beta$  related disease, and a second agent that is (i) a peptide or peptidomimetic that modulates amyloid- $\beta$  fibril formation or induces a prophylactic or therapeutic immune response against amyloid- $\beta$  fibril formation, or (ii) an immune system modulator that prevents or inhibits amyloid- $\beta$  fibril formation.

Group III, claim(s) 79, drawn to the use of a first agent and a second agent in the preparation of a pharmaceutical composition for the treatment or prevention of an amyloid- $\beta$  disease, wherein said first agent prevents or treats amyloid- $\beta$  related disease, and said second agent is (i) a peptide or peptidomimetic that modulates amyloid- $\beta$  fibril formation or induces a prophylactic or therapeutic immune response against amyloid- $\beta$  fibril formation, or (ii) an immune system modulator that prevents or inhibits amyloid- $\beta$  fibril formation.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-III is that they all relate to a pharmaceutical composition for treating a subject comprising a first agent that prevents or treats amyloid- $\beta$  related disease, and a second agent that is (i) a peptide or peptidomimetic that modulates amyloid- $\beta$  fibril formation or induces a prophylactic or therapeutic immune response against amyloid- $\beta$  fibril formation, or (ii) an immune system modulator that prevents or inhibits amyloid- $\beta$  fibril formation. However, WO 99/27944A1 to Schenk teaches methods and compositions for prophylactic and therapeutic treatment of Alzheimer's disease. The compositions comprise an agent(s) that induce(s) a beneficial immune response against an amyloid deposit in the patient, e.g. an A $\beta$  peptide or an antibody thereto (entire document, e.g., abstract). The '944 document also teaches that agents can be administered with other agents that are effective in treatment of amyloidogenic disease (p.25, lines 16-18). Thus, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Amyloid- $\beta$  related diseases:

- a. Alzheimer's disease
- b. Mild cognitive impairment

Art Unit: 1649

- c. Mild-to-moderate cognitive impairment
- d. Vascular dementia
- e. Cerebral amyloid angiopathy
- f. Hereditary cerebral hemorrhage
- g. Senile dementia
- h. Down's syndrome
- i. Inclusion body myositis
- j. Age-related macular degeneration
- k. Hypothyroidism
- l. Cerebrovascular disease
- m. Cardiovascular disease
- n. Memory loss
- o. Anxiety
- p. Apathy
- q. Aggression
- r. Incontinence
- s. Huntington's disease
- t. Amyotrophic lateral sclerosis
- u. Acquired immunodeficiency
- v. Parkinson's disease
- w. Aphasia
- x. Apraxia

- y. Agnosia
- z. Pick disease
- aa. Dementia with Lewy bodies
- bb. Altered muscle tone
- cc. Seizures
- dd. Sensory loss
- ee. Visual field deficits
- ff. Incoordination
- gg. Gait disturbance
- hh. Transient ischemic attack or stroke
- ii. Transient alertness
- jj. Attention deficit
- kk. Frequent falls
- ll. Syncope
- mm. Neuroleptic sensitivity
- nn. Normal pressure hydrocephalus
- oo. Subdural hematoma
- pp. Brain tumor
- qq. Posttraumatic brain injury
- rr. Posthypoxic damage
- ss. Depression
- tt. Delusions

- uu. Illusions
- vv. Hallucinations
- ww. Sexual disorders
- xx. Weight loss
- yy. Psychosis
- zz. A sleep disturbance
- aaa. Behavioral disinhibition
- bbb. Poor insight
- ccc. Suicidal ideation
- ddd. Irritability
- eee. Anhedonia
- fff. Social withdrawal
- ggg. Excessive guilt.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Art Unit: 1649

are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-79.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to a plurality of disease states/pathological conditions with different etiologies, symptoms and treatments.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Third agents:

1. An adrenergic
2. anti-adrenergic
3. Anti-androgen
4. Anti-anginal
5. Anti-anxiety
6. Anticonvulsant
7. Antidepressant
8. Anti-epileptic



Art Unit: 1649

9. Antihyperlipidemic
10. Antihyperlipoproteinemic
11. Antihypertensive
12. Anti-inflammatory
13. Antiobessional
14. Antiparkinsonian
15. Antipsychotic
16. Adrenocortical steroid
17. Adrenocortical suppressant
18. Aldosterone antagonist
19. Amino acid
20. Anabolic steroid
21. Analeptic
22. Androgen
23. Blood glucose regulator
24. Cardioprotectant
25. Cardiovascular
26. Cholinergic agonist
27. Cholinergic antagonist
28. Cholinesterase deactivator or inhibitor
29. Cognition adjuvant or enhancer
30. Dopaminergic

Art Unit: 1649

31. Enzyme inhibitor
32. Estrogen
33. Free oxygen radical scavenger
34. GABA agonist
35. Glutamate antagonist
36. Hormone
37. Hypocholesterolemic
38. Hypolipidemic
39. Hypotensive
40. Immunostimulant
41. Monoamine oxidase inhibitor
42. NMDA antagonist
43. AMPA antagonist
44. Opioid antagonist
45. Potassium channel opener
46. Non-hormonal sterol derivative
47. Post-stroke and post-head trauma treatment
48. Prostaglandin
49. Psychotropic
50. Sedative
51. Sedative-hypnotic
52. Selective adenosine antagonist

- 53. Serotonin antagonist
- 54. Selective serotonin uptake inhibitor
- 55. Serotonin receptor antagonist
- 56. Sodium channel blocker
- 57. Calcium channel blocker
- 58. Steroid
- 59. Stimulant
- 60. Thyroid hormone or inhibitor agents.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-79.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

Art Unit: 1649

corresponding special technical features for the following reasons: The species are structurally and functionally distinct agents, wherein each group itself comprises a genus of potential agents.

The examiner has required restriction between product and process claims. Where applicants elect claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that the reply to this requirement to be complete must include (i) elections of species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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17 March 2008

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